CLAIMS

What is claimed is:

1. A system for the creation or modification of the wear surface of an orthopedic joint within a mammalian body, the system comprising one or more partially or fully preformed polymeric components, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone.

2. A system according to claim 1 wherein one or more of the polymeric components are formed at the time of use, by the use of a curable polymer system adapted to be at least partially cured and partially formed by *ex vivo* molding in order to provide an implantable component adapted to be inserted and positioned *in vivo*, under conditions suitable to permit the implanted component to become finally formed upon reestablishing the natural joint space and in conformance with the opposing bone surfaces of the orthopedic joint site.

3. A system according to claim 1 wherein the polymeric components comprise a plurality of packaged, preformed components adapted to be assembled at the orthopedic joint site in a minimally invasive fashion to provide a final prosthesis having surfaces in conformance with the opposing bone surfaces of the orthopedic joint site.

4. A system according to claim 1 further comprising an *ex vivo* mold having a molding surface adapted to provide a roughened, patterned, and/or contoured surface to the partially preformed component, in a manner sufficient to provide improved retention and fit of the component at the joint site.

5. A system according to claim 4 wherein the mold further provides ancillary means adapted to be incorporated into the preformed component for securing the component once formed in the joint site.

6. A system according to claim 5 wherein the ancillary means comprise one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

7. A system according to claim 4 wherein the contoured surface comprises a contour having one or more protrusions, integral with the preformed component, and formed during the *ex vivo* molding process.

8. A system according to claim 6 wherein the protrusions are adapted to be integrated into the preformed component during the *ex vivo* molding process.

9. A system according to claim 7 wherein the protrusions are comprised of sutures and/or fibrous biomaterials integrally formed with the component itself.

10. A system according to claim 4 further comprising separate means, not associated with the mold itself, for securing the component to the joint site, selected from the group consisting of adhesives, sutures, pins, staples, screws, and combinations thereof.

11. A system according to claim 1 wherein the one or more preformed polymeric component(s) are adapted to be inserted into a joint in a minimally invasive fashion.

12. A system according to claim 2 in which the preformed component(s) and/or corresponding mold(s) are provided in a plurality or range of styles and sizes for selection and use in the surgical field.

13. A system according to claim 1 wherein the implant is adapted for use on the tibial surface of the knee, and provides portions adapted to conform to the shape of the femoral condyle and corresponding medial tibial plateau, lateral tibial plateau, or both.

14. A system according to claim 1 wherein the polymeric component is fabricated from a material selected from the group consisting of polyurethanes, polyureas, hydrogels, polysiloxanes, polyacrylates, and epoxies, and combinations thereof.

15. A system according to claim 14 wherein the polymeric component comprises a polyurethane.

16. A system according to claim 15 wherein the polyurethane is prepared from polyisocyanate(s), short and long chain polyols, and optionally including one or more ingredients selected from the group hydrophobic additive(s), tin and/or amine catalyst(s), and antioxidant(s).

17. A system according to claim 16 wherein the polyurethane comprises aromatic polyisocyanates, PTMO's, and short chain diols.

18. A system according to claim 16 wherein the hydrophobic additive comprises hydroxyl-terminated polybutadiene, and the tin and/or amine catalyst(s) are adapted to promote the isocyanate - hydroxyl reaction preferentially and are selected from the group consisting of UL22, Cotin 222, 1,4-diazabicyclo[2.2.2]octane (dabco), and dibutyltin dilaurate (DBTDL), and combinations thereof.

19. A system according to claim 14, wherein the preformed polymeric component comprises one or more surfaces having attached thereto a biologically active agent selected from the group cytokines, growth factors, autologous growth factors, hydroxyapatite, collagen, and combinations thereof.

20. A system according to claim 14 wherein the surface of the preformed component is provided or modified with reactive groups to promote tissue adhesion.

21. A system according to claim 20 wherein the reactive groups are provided by the polymers used to fabricate the polymeric component, and are selected from amines, hydroxyl groups, or other reactive or hydrogen bonding functionalities.

22. A system for the creation or modification of the wear surface of an orthopedic joint within a mammalian body, the system comprising one or more preformed polymeric components adapted to be positioned within the joint site and one or more flowable biomaterial polymer compositions adapted to be arthroscopically injected into contact with a preformed component and cured *in situ* at the joint site in order to provide a composite implant.

23. A system according to claim 22 wherein the preformed polymeric components comprise an inflatable balloon having a preformed top weight-bearing wear portion and a preformed bottom portion adapted to conform to the shape of supporting bone.

24. A system according to claim 23 wherein the one or more portions of the balloon are fabricated from a natural or synthetic fabric adapted to permit tissue in-growth, and sufficiently permeable to permit air to escape while retaining the curable biomaterial.

25. A system according to claim 24 wherein the fabric is of sufficient permeability to permit physical interpenetration of the flowable polymer.

26. A system according to claim 23 wherein the bottom and/or top portions comprise materials selected from polyurethanes, polyethylenes, polypropylenes, metals, ceramics, biopolymers or the like and combinations thereof.

27. A system according to claim 23 wherein the top and bottom portions are provided with forms corresponding to the shape of a femoral condyle and tibial plateau, respectively.

28. A system according to claim 23 wherein the balloon further comprises a port adapted to fill the balloon with flowable biomaterial *in situ*, in a manner sufficient to force the top portion toward corresponding bone.

29. A system according to claim 23 wherein the bottom portion provides a raised protrusion sufficient to improve retention within the joint site and/or to provide a site for suturing, stapling, pinning, or screwing the portion within the joint site.

30. A system according to claim 22 wherein separate means are provided for securing the preformed component within the joint site.

31. A system according to claim 22, further comprising one or more biologically active agents adapted to be provided on one or more surfaces of the resultant composite implant.

32. A system according to claim 22 wherein the surface of the preformed component and/or resultant composite material are provided or modified with reactive groups to promote adhesion.

33. A system according to claim 32 wherein the reactive groups are either provided by the preformed component itself, or are separately added by suitable surface treatment of the component or resultant composite, and the reactive groups are selected from amines, hydroxyl groups, or other reactive or hydrogen bonding functionalities.

34. A system according to claim 22 in which one or more of the preformed components are provided in a plurality or range of styles and sizes.

35. A system according to claim 22 wherein the one or more flowable biomaterial(s) are adapted to be inserted into a joint using minimally invasive means.

36. A system for the creation or modification of the wear surface of an orthopedic joint within a mammalian body, the system comprising a plurality of packaged, preformed

components adapted to be assembled at the orthopedic joint site in a minimally invasive fashion to provide a final prosthesis having surfaces in apposition to and conformance with the opposing bone surfaces of the orthopedic joint site.

37. A system according to claim 36 wherein one or more of the preformed components are provided with surfaces suitably roughened, patterned, or contoured to provide maximum adhesion and fit when placed, and optionally further fitted and secured, within the joint site.

38. A system according to claim 36, wherein one or more of the preformed components are formed at the time of use by the use of a curable bomaterial adapted to completely cure when preformed and then placed and optionally further fitted or secured inside the joint site.

39. A system according to claim 36 wherein one or more of the preformed components provide means for further securing the component once placed in the joint site.

40. A system according to claim 39 wherein the retention means to secure the component includes the use of tissue adhesives to improve fixation.

41. A system according to claim 39 wherein the retention means comprise one or more protrusions adapted to be sutured, pinned, stapled, screwed or combinations thereof or otherwise mechanically attached into the surrounding soft tissue and/or bone to improve fixation.

42. A system according to claim 41 wherein the protrusions are themselves integral with the preformed component.

43. A system according to claim 42 wherein the protrusions are integrated into a flowable biomaterial during the *ex vivo* molding process used to form the preformed component.

44. A system according to claim 43 wherein the protrusions are comprised of sutures or fibrous materials.

45. A system according to claim 39 wherein means to secure the component are external to it and secured once inside the joint site by the use of adhesives, sutures, pins, staples, screws or the like and combinations thereof to improve fixation to the surrounding soft tissue and/or bone to improve fixation.

46. A system according to claim 36 wherein the one or more preformed component(s) are adapted to be inserted into a joint in a minimally invasive fashion.

47. A system according to claim 36 in which the one or more preformed component(s) are provided in a plurality or range of styles and sizes.

48. A system according to claim 37 wherein the assembled components conform to the shape of the femoral condyle and tibial plateau, medial, lateral or both.

49. A system according to claim 37 wherein the preformed component(s) are fabricated from materials selected from the group consisting of polyurethanes, polyethylenes, polyureas, hydrogels, polysiloxanes, polyacrylates, epoxies, and combinations thereof.

50. A system according to claim 49 wherein the material comprises a polyurethane.

51. A system according to claim 50 wherein polyurethane is prepared from polyisocyanate(s), short and long chain polyols, and optionally including one or more ingredients selected from the group hydrophobic additive(s), tin and/or amine catalyst(s), and antioxidant(s).

52. A system according to claim 51 wherein the polyurethanes are prepared from aromatic polyisocyanates, PTMO's, short chain diols.

53. A system according to claim 52 wherein the hydrophobic additive comprises hydroxyl-terminated polybutadiene, and the tin and/or amine catalyst(s) used promote the

isocyanate - hydroxyl reaction preferentially and are selected from the group consisting of UL22, Cotin 222, 1,4-diazabicyclo[2.2.2]octane (dabco), and dibutyltin dilaurate (DBTDL) or the like and combinations thereof.

54. A system according to claim 36 wherein the preformed components provide one or more surfaces having attached thereto a biologically active agent selected from the group cytokines, hydroxyapatite, growth factors, autologous growth factors, collagen or the like and combinations thereof.

55. A system according to claim 36 wherein the surface of one or more preformed component(s) is provided or modified with reactive groups to promote tissue adhesion.

56. A system according to claim 55 wherein the reactive groups are covalently attached to the polymers used to fabricate the preformed component(s), and are selected from amines, hydroxyl groups, or other reactive or hydrogen bonding functionalities.

57. A system according to claim 36 wherein the preformed component(s) are selected from the group consisting of a) a single preformed component, b) a plurality of components adapted to be layered upon each other at the tissue site, c) a plurality of components adapted to be assembled at the tissue site in an interlocking fashion, such that the components cooperate to provide a respective portion of the first and second major surfaces.

58. A system according to claims 1 or 22 or 36 further comprising the use of one or more additional materials and/or steps adapted to a) prepare the bone surface itself, b) provide a desired interface between bone, component(s), and/or the physiologic environment, and/or c) treat one or more surfaces of the component(s) in order to provide them with different or improved properties as compared to the inherent properties of the material providing the surface.

59. A system according to claim 58 wherein the materials and/or steps are adapted to affect, improve or provide a surface property or function selected from adhesion, lubricity, smoothness, conformance, tissue in-growth, or biocompatibility.

60. A system according to claims 1 or 22 or 36 wherein the system is adapted to be used for repairing a variety of mammalian joints, including human joints selected from the group consisting of the tibial plateau of the knee, the acetabulum of the hip, the glenoid of the shoulder, the acromion process of the shoulder, the acromio-clavicular joint of the shoulder, the distal tibial surface of the ankle, the radial head of the elbow, the distal radius of the forearm, the proximal phalanx surface of the great toe, the proximal metacarpal surface of the thumb, and the trapezium of the wrist.

61. A system according to claim 60 wherein the system is adapted to be used for repairing the tibial plateau of the knee.

62. A system according to claim 60 wherein the system is adapted to be used for repairing the acetabulum of the hip.

63. A system according to claim 13 wherein the implant is provided in the form of a preformed knee implant prepared using an *ex vivo* mold and having a first major surface adapted to be positioned upon the tibial surface, and a second major surface adapted to be positioned against the femoral condyle.

64. A system according to claim 63 wherein the second major surface is provided with a femoral glide path to facilitate its performance *in situ*.

65. A system according to claim 64 wherein the glide path is in the form of a generally central oval depression about 1 mm to about 5mm deep at its lowest point and about 30 mm to about 50 mm in length by 10 mm to 30 mm in width.

66. A system according to claim 63 wherein the implant also includes a raised tibial projection adapted to catch the posterior portion of the tibial plateau *in situ*.

67. A system according to claim 63 wherein the implant has dimensions on the order of between about 40 to about 60 mm in the anterior-posterior dimension, between about 30 mm to about 40 mm in the medial-lateral dimension, and a maximum thickness, at the posterior lip, of between about 10 mm and about 20 mm.

68. A system according to claim 63 wherein the preformed component includes ancillary means for securing the component once formed in the joint site.

69. A system according to claim 68 wherein the ancillary means comprise one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

70. A system according to claim 68 wherein the contoured surface of the preformed component further comprises a contour having one or more protrusions, integral with the preformed component, and formed during the *ex vivo* molding process.

71. A system according to claim 70 wherein the protrusions are adapted to be integrated into the preformed component during the *ex vivo* molding process and comprise sutures and/or fibrous biomaterials integrally formed with the component itself.

72. A system according to claim 68 wherein the ancillary means are selected from the group consisting of adhesives, sutures, pins, staples, screws, and combinations thereof.

73. A system according to claim 70 wherein the implant is preformed in a mold having an anterior cup edge that is substantially perpendicular to the plane of the cup itself, and a posterior mesial edge that is tapered and raised to accommodate the corresponding shape of the tibial spine.

74. A system according to claim 73 wherein the mold is adapted to permits control of sizing, conformance to the joint site, implant thickness and angular correction.

75. A system according to claim 74 where the implant assumes a generally kidney-shaped configuration, adapted to correspond with the tibial surface, and provides a posterior mesial edge portion having an indentation to accommodate the typical shape of the corresponding tibial spine.

76. A system according to claim 15 wherein the polyurethane comprises an isocyanate selected from the group consisting of aromatic, aliphatic and arylakyl diisocyanates, and combinations thereof.

77. A system according to claim 76 wherein the isocyanate is selected from the group consisting of toluene diisocyanates, naphthalene diisocyanates, phenylene diisocyanates, xylylene diisocyanates, diphenylmethane diisocyanates, cyclohexane diisocyanates, cyclohexyl-bis methylene diisocyanates, isophorone diisocyanates and hexamethylene diisocyanates.

78. A system according to claim 63 further comprising a patella-femoral joint form suitable adapted to be formed to, and held against, the femoral bone surface, in order to permit the delivery of curable biopolymer between the form and the bone.

79. A system according to claim 1 wherein the implant is provided in the form of a preformed knee implant prepared using an *ex vivo* mold and having a first major surface adapted to be positioned upon the tibial surface, and a second major surface adapted to be positioned against the femoral condyle, the implant also includes a raised tibial projection adapted to catch the posterior portion of the tibial plateau *in situ*, the implant has dimensions on the order of between about 40 to about 60 mm in the anterior-posterior dimension, between about 30 mm to about 40 mm in the medial-lateral dimension, and a maximum thickness, at the posterior lip, of

between about 10 mm and about 20 mm, the preformed component includes ancillary means for securing the component once formed in the joint site, and the preformed component is fabricated from a polyurethane that comprises an isocyanate comprising a phenylene diisocyanate.